

# Large and Unjustified: Second Circuit Clarifies Pleading Requirements in Reverse Payments Cases

A photograph of a modern building's curved glass facade, showing multiple floors and windows reflecting the sky.

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On May 13—and more than ten years after *Federal Trade Commission v. Actavis*, the leading U.S. Supreme Court case on reverse payment settlements—the Second Circuit for the first time weighed in on whether (and how) antitrust plaintiffs’ identification of a so-called “side deal” between a patent holder and an accused infringer plausibly alleges a “large and unjustified payment.” In particular, the Second Circuit ruled that the plaintiffs in *In re: Bystolic Antitrust Litigation* had failed to “plausibly allege that [the defendant’s] reverse payments were sham and pretextual rather than payments that constituted fair value for goods and services obtained as a result of arms-length dealings.”

The *Bystolic* appeal arises from settlements involving “side deals” between patent-holder Forest Laboratories and several companies seeking to market generic versions of the blood pressure drug Bystolic. The district court ruled that plaintiffs had failed to plausibly allege that any of the alleged “side deals”—i.e., commercial transactions entered into around the time of the settlements—were unjustified or unexplained and thus dismissed plaintiffs’ claims. The plaintiffs appealed and, along with the Federal Trade Commission (“FTC” or the “Commission”) as amicus, urged the Second Circuit to reverse the dismissal.

After a lengthy oral argument in December 2023 during which the panel asked pointed questions of both sides, the Second Circuit ultimately affirmed the dismissal. The decision is notable for at least two reasons. First, the Second Circuit’s lengthy commentary on the

Supreme Court's *Actavis* decision sheds light not just on reverse payments cases involving side deals, but will be instructive for all types of reverse payments cases going forward. Second, the affirmance likely puts the Second Circuit on a collision course with at least the Third Circuit, which arguably applied a more relaxed pleading standard.

Nearly eight pages of the Second Circuit's opinion are dedicated to an in-depth analysis of *Actavis*, concluding with the distillation of "several general principles" from the Supreme Court's decision. In particular, the Second Circuit emphasizes that (1) plaintiffs must plausibly allege under relevant pleading principles that a reverse payment is *both* large *and* unjustified and that (2) for a plaintiff to allege that a payment is unjustified, they "must plausibly allege that the payment is a pretext for nefarious anticompetitive motives rather than made pursuant to traditional settlement considerations."

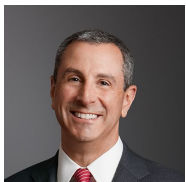
The latter principle, as applied by the Second Circuit in *Bystolic*, would give drug manufacturers substantial latitude to enter into side deals as a way of facilitating settlements of drug patent litigation without facing lengthy and expensive antitrust challenges. But drug manufacturers have good reason to remain wary. The FTC has authority to investigate and challenge reverse payment settlements, and the Commission supported the antitrust plaintiffs' position and urged the Second Circuit to reverse the district court's dismissal.

In addition, drug manufacturers have no assurance that other circuits will follow *Bystolic*. The Third Circuit in *In re Lipitor Antitrust Litigation* previously held that "[t]o plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a 'convincing justification' for the payment." 868 F.2d 231, 256 (3d Cir. 2017). This articulation of the pleading standard appears to set the bar relatively lower than interpreted by the Second Circuit, setting the stage for a circuit split that may well bring the pleading requirements set forth in *Actavis* right back to the Supreme Court.

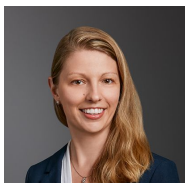


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